

OCT 17 2000

FLUOROSCAN
A HOLOGIC COMPANY

K002198
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510(k) SUMMARY
FluoroScan Profile Imaging System

Submitter Name: FluoroScan Imaging Systems, Inc.

Submitter Address: 650-B Anthony Trail
Northbrook, IL 60062

Contact Person: William J. Engel, Manager Regulatory Affairs

Phone Number: (847) 564-5400

Fax Number: (847) 564-5647

Date Prepared: September 22, 2000

Device Trade Name: FluoroScan Profile

Device Common Name: Radiographic/Fluoroscopic Imaging System

Classification Name: Mobile X-ray System

Predicate Devices: Wuestic C-Quest 4R
OEC/GE Compact 7700
Philips BV300 Series
Seimens Siremobil

Device Description: The Profile C-arm System is a mobile C-arm specifically designed for X-ray imaging.

Intended Use: The FluoroScan Profile System is designed to provide physicians with fluoroscopic and spot exposures for visualization of a patient including, but not limited to, general surgical procedures, orthopedic, critical and emergency care, limited interventional procedures, trauma, pacemaker implantation, respiratory, skeleton and pediatric procedures.

**Technological
Characteristics:**

The FluoroScan Profile is not only similar to the Wuestec C-Quest, it is, in fact, the same identical system (Model # TCA 4 Plus and TCA 4R Plus) manufactured by Technix. The only difference between the two is the OEM distributor's name placed on the system by Technix.

Performance Data:

Results of prototype testing, as well as compliance testing conducted by an independent health physicist on the Profile C-arm Imaging System, indicates conformance to all applicable performance standards promulgated by the FDA for fluoroscopic imaging systems.

Conclusion:

Based on a comparison to other devices determined to be substantially equivalent through the 510(k) premarket notification process and the claim that the Profile device meets the federal performance standard for radiographic/fluoroscopic x-ray systems per 21 CFR 1020.30-1020.32, FluoroScan Imaging Systems, Inc. concludes that the Profile C-arm System is as safe, as effective and performs as well as other legally marketed c-arm devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2000

William J. Engel
Manager, Regulatory Affairs
FluoroScan Imaging Systems
650B Anthony Trail
Northbrook, IL 60062

Re: K002198
FluoroScan Profile FS-9 and FS-9R Model TCA 4 Plus
and TCA 4R Plus
Dated: July 18, 2000
Received: July 20, 2000
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Engel:

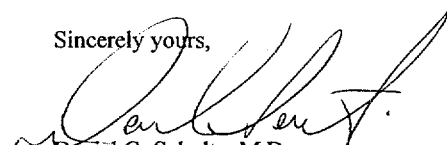
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) NUMBER (IF KNOWN): K002198DEVICE NAME: FluoroScan Profile

INDICATIONS FOR USE:

Indication for Use Statement

The TCA 4 Plus and TCA 4R Plus C-Arm Systems are designed to provide physicians with fluoroscopic and spot exposures for visualization of a patient including, but not limited to, general surgical procedures, orthopedic, critical and emergency care, limited interventional procedures, trauma, pacemaker implantation, respiratory, skeleton and pediatric procedures.

09/22/00
Date

William J. Engel
William J. Engel
Manager, Regulatory Affairs

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002198